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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hai-Quan Mao, et al.

Serial No: 10/047,941

Filed: 15 January 2002

For: *Biodegradable Polymers Chain-Extended by Phosphates, Compositions, Articles and Methods for Making and Using the Same*

Group Art Unit: 1714

Attorney Docket No.: GPT-005.03

Examiner: Szekely, P.

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

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**BRIEF ON APPEAL**

Dear Sir:

This is an appeal to the Board of Patent Appeals & Interferences from the decision of the Examiner finally rejecting claims 135-154. This Appeal Brief follows the Notice of Appeal filed July 8, 2003. Appellants submit this Appeal Brief, in triplicate, and the appropriate fee. A petition for a Five Month Extension of Time, and appropriate fee, accompanies this brief. The appealed claims are as set forth in Appendix A.

**1. REAL PARTY IN INTEREST**

Appellants Zhao and English have assigned their rights in the instant patent application to Guilford Pharmaceuticals, Inc., recorded at Reel 013080, Frame 0760. Appellants Mao and Leong have assigned their rights in the instant patent application to Johns Hopkins University

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## 2. RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any interferences or other appeals that will directly affect or be directly affected by, or have a bearing on, the Board's decision in this appeal.

## 3. STATUS OF CLAIMS

Claims 134-154 were finally rejected in the Office Action dated January 9, 2003. Accordingly, claims 134-154 are on appeal. A current version of the pending claims is set forth in the attached Appendix A, in accordance with 35 C.F.R. 1.192(c)(9).

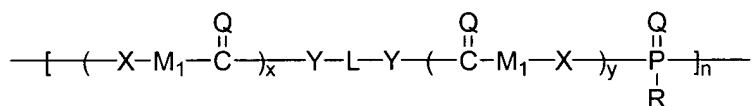
## 4. STATUS OF AMENDMENTS

No amendments have been filed or entered subsequent to the final rejection.

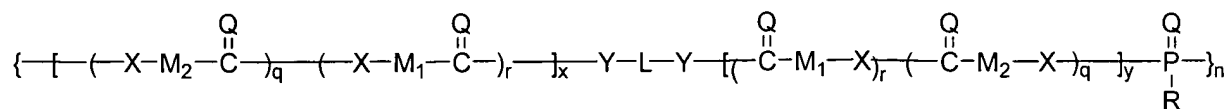
## 5. SUMMARY OF INVENTION

The polymers and polymer compositions of the instant application include phosphorus containing polymers that are biocompatible. Independent claim 134 is directed to a polymer composition, comprising a polymer comprising the recurring monomeric units shown in formula I or II:

I



II

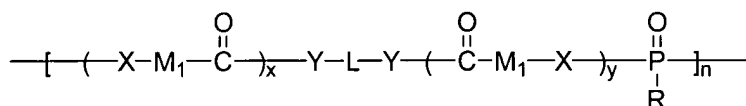


As set forth in claim 134, with support as indicated in the specification, X is -O- or -NR'-, where R' is H or alkyl. (Specification at page 5, line 16). M<sub>1</sub> and M<sub>2</sub> are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms. (Specification at page 5, lines 16-21). Y represents -O-, -S- or -NR'-, where R' is H or alkyl. (Specification at page 5, line 22). Q is O or NR', where R' is H or alkyl. L represents a

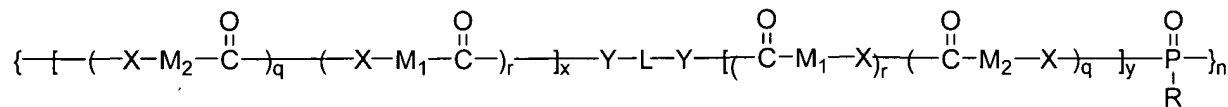
non-interfering substituent. R represents H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy. (Specification at page 5, lines 25-26). The molar ratio of x:y is about 1, the molar ratio n:(x or y) is between about 200:1 and 1:200, and the molar ratio q:r is between about 1:99 and 99:1. (Specification at page 5, lines 27-28, page 6, lines 1-2). This claimed polymer is biocompatible.

Independent claim 147 is directed to a polymer composition that includes at least one biologically active substance, and a polymer having the recurring monomeric units shown in formula I or II:

I



II



As set forth in claim 134, with support as indicated in the specification, X is -O- or -NR'-, and where R' is H or alkyl. (Specification at page 5, line 16). M<sub>1</sub> and M<sub>2</sub> are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms. (Specification at page 5, lines 16-21). Y represents -O-, -S- or -NR'-, where R' is H or alkyl. (Specification at page 5, line 22). L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group. (See, for example, specification at page 9 line 27, page 10 lines 1-12). R represents H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy. (Specification at page 5, lines 25-26). The molar ratio of x:y is about 1, the molar ratio n:(x or y) is between about 100:1 and 1:100; and the molar ratio q:r is between about 1:99 and 99:1. (Specification at page 14 lines 6-17). This claimed polymer is biocompatible.

## 6. ISSUES

Appellants respectfully submit the following issues for review:

1. The rejection of claims 134-146 under 35 U.S.C. 112, first paragraph as to whether the specification and drawings support the recitation of a Q moiety and the recitation of the L moiety as defined by these claims.

2. The rejection of claims 147-154 under 35 U.S.C. 112 first paragraph as to whether the specification and drawings support the recitation of the L moiety as defined by these claims.

3. The rejection of claims 134-146 under 35 U.S.C. 112 first paragraph as to whether the specification and drawings enable a person skilled in the art to make and use a polymer with an Q moiety and an L moiety as defined by these claims.

4. The rejection of claims 147-154 under 35 U.S.C. 112 first paragraph as to whether the specification and drawings enable a person skilled in the art to make and use a polymer with an L moiety as defined by these claims.

## 7. GROUPING OF CLAIMS

The claims do not stand or fall together. The issues raised by the rejection of claims 134-146 are different from those raised by the rejection of claims 147-154. Therefore, claims 134-146 should be treated as a group, and claims 147-154 should be treated as a separate group. This grouping of claims is for the purposes of this appeal only, and should in no way be construed as a characterization, acquiescence, narrowing, or surrender of any subject matter, claimed or otherwise.

## 8. ARGUMENT

### Issue 1.

Claims 134-146 stand rejected under U.S.C § 112, first paragraph. In particular, the Examiner contends that claims 134-146 contain “subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Appellants respectfully traverse this rejection. Appellants assert that the moiety Q in these claims, encompassing O or NR’, is adequately described by the instant disclosure. Appellants respectively assert that a person of ordinary skill in the art would appreciate that NR’ as recited in claim 134 could be used in place of O in the claimed invention.

Appellants further assert that the moiety L in these claims, encompassing a non-interfering substituent, as of the priority date of the instant application, is adequately described by the instant disclosure. Appellants assert that a person of skill in the art would recognize the moiety L as recited in claim 134 is supported by the instant disclosure at, for example, pg. 10 lines 1-17. Accordingly, Appellants respectfully request reconsideration and withdrawal of this rejection.

Issue 2.

Claims 147-154 stand rejected under U.S.C § 112 first paragraph. In particular, the Examiner contends that claims 147-154 contain “subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Appellants respectfully traverse this rejection.

Appellants respectfully note the rejection of claims 134-154 is based, at least in part, on the description of the moiety Q in these claims, which is not recited in claims 147-154. Therefore, Appellants respectfully assert that claims 147-154 are separately patentable from claims 134-146.

Appellants further assert that the moiety L in these claims, encompassing a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group or a polymeric group, as of the priority date of the instant application, is adequately described by the instant disclosure. Appellants assert that a person of skill in the art would recognize the moiety L as recited in claim 147 is supported by the instant disclosure at, for example, pg. 10 lines 1-17. Accordingly, Appellants respectfully request that this rejection be reversed.

Issue 3.

Claims 134-146 stand rejected under U.S.C § 112 first paragraph. The Examiner contends that the specification “does not reasonably provide for enablement for Q being oxygen or NR’, wherein R is H or alkyl, or for L being any non-interfering substituent, branched or straight chain aliphatic group of undetermined length, a cyclic aliphatic group, a divalent aryl group or a polymeric group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention

commensurate in scope with these claims.” Appellants respectfully traverse this rejection. Appellants assert that the disclosure contains sufficient information as to enable a person skilled in the chemical arts to make and use the claimed invention, without undue experimentation. Appellants assert that there is sufficient guidance, for example, in the examples of the instant disclosure, pages 38-45, to enable a person skilled in the art to make polymers where Q is O or NR’, and/or L is a non-interfering substituent, as recited in claim 134. Accordingly, Appellants respectfully request that this rejection be reversed.

#### Issue 4.

Claims 147-154 rejected under U.S.C § 112 first paragraph. The Examiner contends that the specification “does not reasonably provide for enablement for Q being oxygen or NR’, wherein R is H or alkyl, or for L being any non-interfering substituent, branched or straight chain aliphatic group of undetermined length, a cyclic aliphatic group, a divalent aryl group or a polymeric group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.” Appellants respectfully traverse this rejection.

Appellants respectfully note the rejection of claims 134-154 is based, at least in part, on the description of the moiety Q in these claims, which is not recited in claims 147-154. Therefore, Appellants respectfully assert that claims 147-154 are separately patentable from claims 134-146.

Appellants assert that the disclosure contains sufficient information as to enable a person skilled in the chemical arts to make and use the claimed invention, without undue experimentation. Appellants assert that there is sufficient guidance, for example, in the examples of the instant disclosure, pages 38-45, to enable a person skilled in the art to make polymers where L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group, as recited in claim 147. Accordingly, Appellants respectfully that this rejection be reversed..

#### **CONCLUSION**

The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. Should an extension of time be required, Appellants hereby petition for same and

request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account, **No. 06-1448**.

Date: February 9, 2004

**Customer No: 29755**

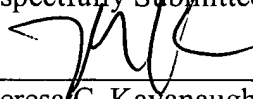
Patent Group

Foley Hoag LLP

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Respectfully Submitted,



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Theresa C. Kavanaugh

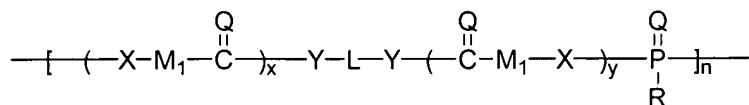
Agent for Appellants

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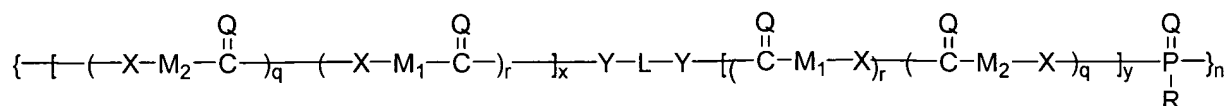
## 9. APPENDIX A

134. A polymer composition, comprising a polymer comprising the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, wherein R' is H or alkyl;

M<sub>1</sub> and M<sub>2</sub> are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-, wherein R' is H or alkyl;

Q is O or NR', wherein R' is H or alkyl;

L is a non-interfering substituent;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said polymer is biocompatible before and upon biodegradation.



135. The polymer composition of claim 134, wherein L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group.

136. The polymer composition of claim 135, wherein L is an alicyclic polymer.

137. The polymer composition of claim 136, wherein Q is O.

138. The polymer composition of claim 136, wherein L is selected from a polymer of ethylene glycol or a polymer of propylene glycol.

139. The polymer composition of claim 136 wherein L is a copolymer of ethylene glycol and propylene glycol.

140. The polymer composition of claim 134, wherein said polymer composition is in the form of a block copolymer.

141. The polymer composition of claim 134, wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group or a heterocycloxy group.

142. The polymer composition of claim 135, wherein for each occurrence of  $M_1$  and  $M_2$  in said monomeric unit,  $M_1$  and  $M_2$  is optionally a methyl-substituted -CH- group or a methylene group, Q is O and X is -O-.

143. The polymer composition of claims 134, 140, or 142, further comprising a biologically active substance.

144. The polymer composition of claim 143, wherein said biologically active substance is a neoplastic agent or a local anesthetic.

145. The polymer composition of claim 144, wherein said neoplastic agent is paclitaxel.

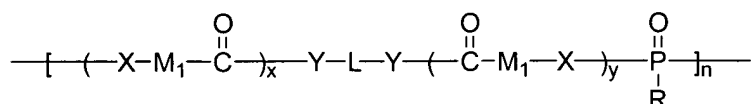
146. The polymer composition of claim 144, wherein said local anesthetic is lidocaine.

147. A polymer composition comprising:

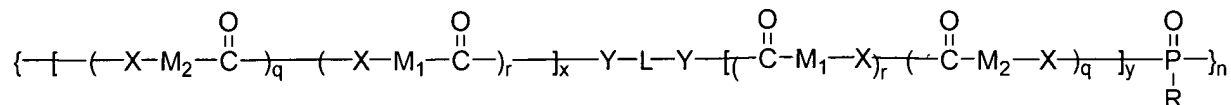
(a) at least one biologically active substance, and

(b) a polymer having the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M<sub>1</sub> and M<sub>2</sub> are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 100:1 and 1:100; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said polymer is biocompatible before and upon biodegradation.

148. The polymer composition of claim 147, wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group or a heterocycloxy group.

149. The polymer composition of claim 148, wherein L is an alicyclic polymer.

150. The polymer composition of 149, wherein:  $M_1$  and  $M_2$  are each an alkylene or alkoxy group; L is an alkylene group; X is -O-; and R is an alkoxy group.

151. The polymer composition of claim 147, wherein said polymer composition is in the form of a block copolymer.

152. The polymer composition of claims 147, 150 or 151, wherein said biologically active substance is a therapeutic drug or pro-drug.

153. The polymer composition of claim 152, wherein said biologically active substance is paclitaxel.

154. The polymer composition of claim 152, wherein said biologically active substance is an amide local anesthetic or an ester local anesthetic.